# TSCA HEALTH & SAFETY STUDY COVER SHEET

MR 6270

**TSCA CBI STATUS:**

**X-CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)**

Clearly mark the confidential information with bracketing and check the box in the appropriate section (☐ *Contains CBI*). Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

**1.0 SUBMISSION TYPE** X - *Contains CBI*

☐ 8(d) **X 8(e)** ☐ FYI ☐ 4 ☐ OTHER: Specify 8EHQ-0598-14176S

X- Intial Submission -Follow-up Submission -Final Report Submission

Previous EPA Submission Number or Title if update or follow-up: Docket Number, if any: #

☐ continuation sheet attached

**2.1 SUMMARY/ABSTRACT ATTACHED**
(may be required for 8(e): optional for §4, 8(d) & FYI)
X - YES -NO

**2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID**
Cert# P 917 006 732
98-2-6

**2.3 FOR EPA USE ONLY**

**3.0 CHEMICAL/TEST SUBSTANCE IDENTITY** X-*Contains CBI*

*Reported Chemical Name (specify nomenclature if other than CAS name):*

CAS#: N/A

Purity _____%

**Confidential Information Has Been Sanitized**

X - Single Ingredient

☐ Commerical/Tech Grade

☐-Mixture *Trade Name:* _____ *Common Name:* Arylurazole

98 MAY 15 AM 8:11 RECEIVED OPPT NCIC

**4.0 REPORT/STUDY TITLE** - *Contains CBI*

Developmental Toxicity Screening in Rats after Oral Administration – Study # T2061726

☐ Continuation sheet attached

**5.1 STUDY/TSCATS INDEXING TERMS**

[CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

**5.2 STUDY/TSCATS INDEXING TERMS** (see instructions for 4 digit codes)

STUDY TYPE: _TOX_ SUBJECT ORGANISM (HE, EE only): RATS ROUTE OF EXPOSURE (HE only): ORAL VEHICLE OF EXPOSURE (HEonly)__

*Other:* Developmental *Other:* _____ *Other:* _____ *Other:* _____

**6.0 REPORT/STUDY INFORMATION** -*Contains CBI* -Study is GLP

Laboratory Bayer Tox Lab Wuppertal Report/Study Date: 4/9/98

Source of Data/Study Sponsor (if different than submitter) Bayer AG Number of pages 0

☐ continuation sheet attached

**7.0 SUBMITTER INFORMATION** ☐ *Contains CBI*

Submitter: Donald W. Lamb, Ph.D Title: V. P., Prod. Safety & Reg. Affrs Phone: 412-777-7431

Company Name: Bayer Corporation Company Address: 100 Bayer Road

Pittsburgh, PA 15205-9741 Submitter Address (if different): _____

Technical Contact: Donald W. Lamb, Ph.D Phone: (412)777-7431

☐ continuation sheet attached

**8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS** ☐ *Contains CBI*

Test substance is a developmental herbicidal agent and only the results are being reported.

COMPANY SANITIZED

98 MAY 11 PM 12:33

☐ continuation sheet attached

**Submitter Signature:** Donald W. Lamb **Date:** 5/6/98



8EHQ-98-14176

86980000043

TSCA CBI STATUS:

- CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

Clearly mark the confidential information with bracketing and check the box in the appropriate section (*Contains CBI*). Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

Submitter Tracking Number/Internal ID

P917006732
98-2-6

CONTINUED FROM COVER SHEET SECTION # 2.1 **Confidential Information Has Been** Sanitized

5 inseminated Wistar rats each were daily treated orally by gavage with 100 or 1000 mg - 6574/kg body weight/day in 0.5 % carboxymethylcellulose in demineralized water from day 6 to day 19 p.c. The fetuses were delivered by cesarean section on day 20 p.c. Investigations were performed on the general tolerance of the test compound by the females as well as on its effects on intrauterine development (pregnancy rate, number of fetuses and resorptions, external findings in the fetuses, fetal weight and fetal skeletal malformations and variations (wavy ribs only)).

## Adverse Effects and Scientific Evaluation

One female of the 1000 mg/kg group was killed in moribund conditions on day 15 p.c. The remaining females of the 1000 mg/kg group showed piloerection during the last days of gestation. Furthermore, weight loss and decreased feed intakes were evident during the treatment period in the 1000 mg/kg group. In addition, increased water intakes and urination occurred at the 1000 mg/kg level.
Gross necropsy revealed enlarged and light discolored kidneys in all females of the 1000 mg/kg group.

The gestation rate was severely decreased by the total resorption of all females with implantation sites in the 1000 mg/kg group. Thus, there were no fetuses available at this dose level.
The gestation rate, the resorption rate and correspondingly the number as well as the external appearance of fetuses were unaffected at the 100 mg/kg level. The fetal weight was distinctly decreased at the 100 mg/kg level.
Skeletal evaluation of the fetuses revealed common skeletal malformations in 50 % of the fetuses (dysplasia of limb bones, all litters affected). Furthermore, the skeletal variation wavy ribs occurred in 86 % of the fetuses.

Thus, distinct maternal toxicity occurred at the 1000 mg/kg level while there was no indication of maternal toxicity at the 100 mg/kg level.
Developmental toxicity was evident by decreased fetal weights as well as skeletal malformations and variations at the 100 mg/kg level.

In this study, all females of the 1000 mg/kg group resorbed all implants. Furthermore, decreased fetal weights as well as skeletal malformations and variations occurred at the 100 mg/kg level.